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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/858,198	05/14/2001	Rudolf H. Aebersold	P-IS 4693	2506
41552	7590	11/28/2005	EXAMINER	
MCDERMOTT, WILL & EMERY 4370 LA JOLLA VILLAGE DRIVE, SUITE 700 SAN DIEGO, CA 92122			CEPERLEY, MARY	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 11/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/858,198	<b>Applicant(s)</b> AEBERSOLD ET AL.	
	<b>Examiner</b> Mary (Molly) E. Ceperley	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13,76-127,132,134 and 138-146 is/are pending in the application.
- 4a) Of the above claim(s) 87-89,91,100-102,104 and 141 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 76-86,90,92-99,103,105-127,132,134,135,138-140 and 142-146 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>08/24/05</u> . | 6) <input type="checkbox"/> Other: _____  |

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**1)** A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 24, 2005 has been entered.

**2)** In view of the papers filed August 24, 2005, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by the addition of Beate Rist, George J. Vella, Subhasish Purkayastha and Sasi Pillai as inventors.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

**3)** The following claims are pending and under active prosecution: 76-86, 90, 92-99, 103, 105-127, 132, 134, 135, 138-140 and 142-146. Applicants should verify this statement since it appears to be at odds with the statement made by applicants in the first paragraph of the August 24, 2005 Remarks.

**4)** The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**5)** Although specific claims may be discussed in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

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**6)** Claims 121-127, 132, 143, 135 and 138-146 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**a)** It is unclear what is meant by the term "two compositions" of claim 142. Is a combination of two separate compositions being claimed? Are each of the two compositions "differentially isotopically labeled" relative to each other? Or is the claim meant to be drawn to a composition comprised of two (sub)compositions wherein each of the (sub)combinations is comprised of multiple moieties which are differentially labeled relative to each other? Exactly what is meant by the "two compositions" of claim 142 also impacts the interpretation of each of claims 143 and 144, i.e. it is unclear what is meant by "one of said compositions".

**b)** In claims 121, 138 and 142, it is unclear what is meant by the term "the leucyl group" since no part of the structure is specifically defined as a "leucyl group".

**c)** Claims 132, 134 and 135 are improperly dependent from canceled claims.

**d)** For claims 121, 138 and 142, it would appear that the "leucyl group" should be designated as containing an isotope tag rather than as the "leucyl group...is an isotope tag". See claims 145 and 146.

**7)** Claims 142-144 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reason stated in paragraph **6)** of the final rejection. Applicants state that claim 142 recites "a specific structure disclosed in the specification, for example, in Figure 1" (Remarks, paragraph bridging pages 12 and 13). This statement is irrelevant however, in light of the fact that claim 142 is drawn to "two compositions" and is not drawn to "a specific structure". Further, Figure 1 shows the reaction of a single structure and in no way is related to "two compositions".

**8)** Claims 76-86, 90, 92-99, 103 and 105-120 are rejected under 35 U.S.C. 112, first paragraph, for the reason stated in paragraph **5)** of the April 07, 2004 Office action and as further maintained in

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paragraph **7)** of the final rejection (scope of enablement). Although applicants argue on page 13 of the Remarks that the specification describes a variety of "tags", "cleavable functional groups" and "reactive groups", this rejection is a scope of enablement rejection based on a lack of information on how to make and use all of the described compositions. The examiner does not agree that "one skilled in the art would have readily understood appropriate chemistries for particular functional groups based on the teachings in the specification and what was well known to those skilled in the art" (see the discussions appearing in the last two Office actions). An issue for appeal appears to have been reached for this rejection.

**9)** The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**10)** Claims 76-86, 90, 92-99, 103, 105-127, 132, 134, 135, 138-140 and 142-146 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 76-105 of copending Application No. 10/615,320. Although the conflicting claims are not identical, they are not patentably distinct from each other because independent claims 76 and 94 of application no. 10/615,320 encompass the compositions of the claims of this application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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**11)** Claims 76-86, 90, 92-99, 103, 105-127, 132, 134, 135, 138-140 and 142-146 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 76-105 of copending Application No. 11/142,720. Although the conflicting claims are not identical, they are not patentably distinct from each other because independent claims 76 and 94 of application no. 11/142,720 encompass the compositions of the claims of this application.

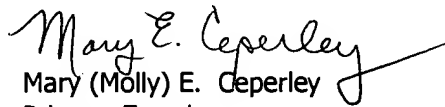
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**12)** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 22, 2005

  
Mary (Molly) E. Ceperley  
Primary Examiner  
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